REMARKS

Claims 1-7 which are under consideration are directed to a manufactured β-chitin complex comprising an intercalation compound formed by using as a host a β-chitin, and introducing a guest compound between the stacked sheets of chitin molecular chains forming the crystal lattice of the β-chitin. The guest compound has a functional group that can form a hydrogen bond with a hydroxyl group and/or an amide group. In other words, the guest compound is a polar molecule. The guest compound is interposed between mono-molecular chitin sheets that form the crystal lattice of chitin, so that the entire structure of the crystal composed of chitin molecules in the complex is distorted, compared to the structure of naturally occurring β-chitin crystal. That distortion is reflected in the increase in the spacing between chitin molecular chain sheets, as shown by X-ray diffraction in Fig. 1 and Fig. 2. The claimed complex is useful as a drug delivery system in which the drug is the guest compound introduced into the β-chitin crystal lattice. As noted in the definition for intercalation compounds cited from the IUPAC Gold Book in the final Office Action, intercalation compounds result from "reversible inclusion, without covalent bonding, of one kind of molecule in a solid matrix of another compound, which has a laminar structure." The claimed complex is useful as a drug delivery system because of this reversible inclusion of the guest compound in the β-chitin structure.

As stated on page 3, line 3, of the specification of the present application, an inclusion complex or intercalation compound of water and β-chitin (i.e., β-chitin hydrate) is known. This hydrate is the only known naturally occurring intercalation compounds of β-chitin. In addition, the inventors named in the present application have previously reported the preparation of inclusion compounds or intercalation compounds of β-chitin and acrylic acid, a linear monoamine or a linear diamine (page 3, lines 6-13.) However, these known inclusion compounds presented problems in the limited utility of the guest compound and the difficulties in production of the inclusion compounds.

Rejection under 35 USC §102

Claims 1-5 and 7 stand rejected under 35 USC §102(b) as being anticipated by McCandliss et al. as evidenced by Falini et al. McCandliss et al. is cited for disclosing a naturally occurring chitin-protein complex (column 1, lines 13-14), and for disclosing that the material is prepared from "suitable chitin-containing material biomass material, for example mollusks (column 5, lines 38-43.)" Falini et al. is cited for teaching that chitin from mollusk shells is in the form of β-chitin. The Office Action further cites Falini et al. for disclosing "thin layers of β-chitin sandwiched between two thicker layers of silklike proteins" in the nacre mollusk (page 2, left column, lines 8-13.) Falini et al. is further cited for disclosing the chitin-protein complex to exist as "intralamellar sheets". The Office Action states that these sheets meet the definition of an intercalation compound, and cites in this context the definition of "intercalation compound" from the IUPAC Gold Book.

Applicants submit that the rejection of record appears to lose sight of the disclosure of McCandliss et al. by focusing more intently on Falini et al. McCandliss et al. aims to produce a chitin-protein complex which is nematocidally active. A significant benefit and advantage of the invention in McCandliss et al. is that it provides a useful means of using waste material from the crab fishing industry in the Chesapeake Bay. All of the examples specifically described with test data in McCandliss et al. use crabshells obtained from crab meal processing waste (Examples 1, 2, 3, 4, 6, 7 and 8, specifically column 9, line 4.) Crab is not a mollusk and contain α-chitin which does not have a lamellar structure. Therefore the core of the disclosure of McCandliss et al. does not pertain to β-chitin, which is produced from mollusks, as noted in the Office Action. McCandliss et al. does make the broad statement that the "chitin-protein complex of this invention can be prepared from any suitable chitin-containing biomass raw material", such suitable materials including but not being limited to invertebrate marine organisms having visible shells, examples of which are arthropods including crustaceans, mollusks, marine benthic organisms and krill fish (column 5, lines 39-44.) Preferred is shellfish waste from "crustaceans such as crabs, lobsters, crayfish, shrimp and prawns" (column 5, lines 44-46.)

The chitin-protein complex of McCandliss et al. is prepared by "mild acid hydrolysis of crustacean shell wastes, with or without recovery of carbon dioxide and other volatile gases

produced during demineralization and partial protein degradation" (column 4, lines 35-40.) Applicants submit that there is insufficient basis to ascribe to the chitin-protein complex which is the invention in McCandliss et al the structure described in Falini et al. for β-chitin in mineralized biological systems. The chitin-protein complex of McCandliss et al. results from demineralization of crustacean shell wastes, whereas the studies of Falini et al. pertain to chitin in mineralized biological systems.

More importantly, there is no hint in the disclosure of McCandliss et al, with or without further interpretation based on Falini et al., that the chitin-protein complex of McCandliss is an intercalation compound. The chitin-protein complex obtained from crab shells, which are the only source of chitin used in all the examples of McCandliss (other than Example 5 which isolates a chitin-protein complex from dried fungal biomass), certainly is not lamellar since it is not formed from β-chitin. Since McCandliss et al. did not report obtaining a chitin-protein complex from sources other than crabshells or dried fungal biomass, the reference provides no basis for ascribing to such chitin-protein complex the structures cited in Falini et al. for β-chitin mineralized biological systems.

McCandliss et al. also mentions that there are other types of chitin-protein complexes, but that they differ from the chitin-protein complex of the invention of McCandliss et al. Specifically, the chitin-protein complex of McCandliss et al. differs from the chitin-protein complex resulting from the demineralization of crabshells by chelating agents and from the chitin-protein complex isolated from fungal residues (column 6, lines 54-60; also Example 3 and Example 5.) In view of this acknowledged existence of different forms of chitin-protein complexes, there is even less basis for ascribing to the chitin-protein complex of the invention of McCandliss et al. the structure described in Falini et al. for β-chitin in mineralized biological systems.

It is respectfully requested that the rejection of claims 1-5 and 7 over McCandliss et al. be reconsidered and withdrawn for all the reasons set forth above.

Rejection under 35 USC §103

Claims 1-7 were rejected under 35 USC §103 as being unpatentable over Drohan et al. in view of Kim et al. Drohan et al. is cited for disclosing a supplemented chitin hydrogel wherein the chitin serves as a carrier vehicle for various compounds. Acknowledging that Drohan et al. does not specifically disclose β-chitin, the Office Action cites Kim et al. for teaching that β-chitin is a good candidate material for uses in medical implant devices, wound dressings, drug delivery, etc. (page 2368, left column, lines 13-17.) The conclusion is set forth in the Office Action that it would have been obvious to one of ordinary skill in the art to combine the invention of Drohan et al. with the teaching in Kim et al. of the specific β-chitin.

As noted above, it has long been known that β-chitin occurs as a hydrate, i.e., a β-chitin crystal intercalated with water as a guest compound.) Kim et al. merely describes the general physical and chemical properties of β-chitin hydrate, and does not disclose β-chitin intercalation compounds with guest compounds other than water.

Applicants submit that even if one of ordinary skill in the art were to be motivated to combine the teachings of Drohan et al. with those of Kim et al. as suggested in the Office Action, the result would not be the manufactured β-chitin complex claimed herein. No combination of the teachings of these two references would lead to an "intercalation compound" as claimed by Applicants, in which a specifically defined guest compound has been introduced into the spaces between the stacked sheets of chitin molecular chains which form the crystal lattice of β-chitin.

It is respectfully requested that the rejection of the claims over Drohan et al. in view of Kim et al. be reconsidered and withdrawn.

Applicants believe that the application is in condition for allowance. However, should the Examiner believe that there is any remaining issue and it may be resolved to place the application in condition for allowance, the Examiner is invited to contact Applicants' attorney at the telephone number listed below.

In the event this response is not considered to be filed timely, Applicants hereby petition for an appropriate extension of the time for reply. The fee for such petition for extension of time may be charged to Deposit Account No. 502081. This reply being filed within two months of the mailing date of the final Office Action, the shortened statutory period will expire on the day an Advisory Action is mailed, if the Advisory Action is not mailed until after the end of the three-month shortened statutory period.

Respectfully submitted,

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